

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CARDINAL HEALTH, INC.,

Petitioner,

v.

NATIONAL BOARD OF MEDICAL
EXAMINERS,

Respondent.

Civil Action No. 2:20-mc-00057-BMS

**MEMORANDUM IN OPPOSITION TO CARDINAL HEALTH’S MOTION TO
COMPEL PRODUCTION OF DOCUMENTS BY NON-PARTY NBME, AND IN
SUPPORT OF NBME’S CROSS-MOTION TO QUASH CARDINAL HEALTH’S
RULE 30(B)(6) DEPOSITION SUBPOENA**

Years after the underlying litigation began and shortly before the close of discovery, Cardinal Health, Inc. (“Cardinal”) wondered if test questions developed by the National Board of Medical Examiners (“NBME”) for a general medical licensing exam might somehow be relevant to claims asserted against Cardinal and other wholesale drug distributors relating to the opioid crisis in West Virginia. On March 27, 2020, Cardinal issued a sweeping non-party subpoena that would require NBME to produce confidential questions and answers from the United States Medical Licensing Examination (“USMLE”). Cardinal’s subpoena called for 24-years’-worth of documents to be produced in just two weeks, at a time when NBME’s offices are closed and NBME is confronting significant operational challenges due to the pandemic.

Cardinal served a second subpoena on April 17, 2020, impermissibly calling for Philadelphia-based NBME to produce a Rule 30(b)(6) deponent in West Virginia to address a broad range of topics from the past two-and-a-half decades. An amended subpoena was issued on April 30, 2020, moving the deposition to Philadelphia.

NBME objected to the document subpoena but produced some documents following a meet-and-confer between counsel. NBME also objected to the deposition subpoena.

Through this miscellaneous action, Cardinal seeks to compel NBME to produce secure USMLE test questions and answers that jurisdictions across the nation rely on for licensure purposes. If NBME produces its confidential questions, they could be disclosed to literally *thousands* of individuals in *thousands* of different cases even if designated “Highly Confidential,” thereby jeopardizing the integrity of the USMLE exam. The resulting harm would be far-reaching, injuring not only NBME, but examinees, state licensing authorities, and the general public.

Cardinal asks this Court to transfer its motion to compel production of documents to the West Virginia court where the underlying lawsuit is pending, or, alternatively, to grant the motion to compel. This brief responds to Cardinal’s motion to compel. It also supports NBME’s cross-motion to quash Cardinal’s deposition subpoena, filed with this brief.

Cardinal’s subpoenas are based on the misguided premise that USMLE questions about “pain management” somehow evidence the standard of care for doctors in West Virginia when prescribing opioids. Because Cardinal has failed to establish any “exceptional” ground to warrant a transfer, as it must, and because disclosure of confidential exam questions would unduly burden and harm NBME, this Court should decline to transfer Cardinal’s motion to compel and deny the motion. Likewise, the Court should quash Cardinal’s Rule 30(b)(6) deposition subpoena.

BACKGROUND

A. The National Board of Medical Examiners

NBME is a nonprofit organization located in Philadelphia. Declaration of Ken Ridgley (“Ridgley Decl.”), ¶ 2. NBME has no connection to Cardinal and nothing to do with the underlying lawsuit. *Id.*

NBME develops and administers the USMLE, a standardized test designed to assess the ability of a medical school student or graduate to apply the knowledge, concepts, and principles needed to provide safe and effective patient care. *Id.* ¶ 3. The exam is designed to evaluate broad-based medical knowledge and skills to help ensure minimum competency.¹ *Id.* It does not establish the general standard of care for doctors, much less for doctors whose practices focus on pain management. *Id.* Jurisdictions across the country rely on USMLE as part of their physician licensure process, requiring prospective doctors to pass the exam before they may practice medicine unsupervised. *Id.* ¶ 4.

The USMLE is comprised of three “Steps,” taken at different times over the course of an individual’s graduate medical education: Step 1, Step 2 (which includes Step 2 Clinical Knowledge (“CK”) and Step 2 Clinical Skills (“CS”)), and Step 3. *Id.* ¶ 5. Except for Step 2 CS, which evaluates communication and clinical skills using interactions with role-playing “standardized” patients, each exam consists primarily of multiple-choice questions. *Id.* For example, Step 2 CK is a nine-hour test with roughly 315 multiple-choice questions. *Id.* The questions at issue in Cardinal’s motion to compel are from Step 1, Step 2 CK, and Step 3.

Developing USMLE questions is a time-consuming and expensive process that requires input from subject matter experts across the country, numerous meetings, and support from NBME editors and other technical staff. *Id.* ¶ 7. It costs at least \$500,000 to create a single exam form, and approximately \$3,000 to develop a single multiple choice question and set of potential answers. *Id.* On average, it takes two years to develop each multiple-choice question on the Step 1, Step 2 CK, or Step 3 USMLE exams. *Id.*; *cf. Am. Bd. of Internal Med. v. Von Muller*, No. 10-

¹ USMLE questions address a wide range of medical subjects and conditions; no content area relates specifically to “pain management.” *See* Ridgley Decl. ¶ 6.

cv-2680, 2012 WL 2740852, at *5 (E.D. Pa. 2012) (“[I]t can take as long as several years to develop a suitable test question.”); *Ass’n of Am. Med. Colleges v. Mikaelian*, 571 F. Supp. 144, 154, 157 (E.D. Pa. 1983) (MCAT questions “are the result of years of painstaking research and testing”) (enjoining unauthorized disclosure of questions), *aff’d mem.*, 734 F.2d 3 (3d Cir. 1984).

The USMLE is a “secure” test, meaning that questions are kept confidential before and after an exam is administered. Ridgley Decl. ¶ 8. USMLE questions are registered with the United States Copyright Office pursuant to special regulations that exempt “secure tests” from the Copyright Act’s usual requirement of leaving a deposit copy with the Copyright Office.² *See id.*; 37 C.F.R. § 202.20(c)(2)(vi). To register a pool of questions, one or more NBME employees travel to Washington, D.C. to participate in an item-by-item review by a Copyright Office examiner, with the questions displayed on an NBME computer. Ridgley Decl. ¶ 8; *see also* 85 Fed. Reg. 27296, 27297 (May 8, 2020) (noting that the Copyright Office “has long provided special registration procedures for ‘secure tests’ that require the maintenance of confidentiality of their contents”). The regulations are designed to “afford protection” to secure tests, “the beneficial purpose of which would be defeated” if copies were available for review. *Nat’l Conf. of Bar Exam’rs v. Multistate Legal Studies*, 692 F.2d 478, 484 n.6 (7th Cir. 1982).

Confidentiality of exam content is critical because—as is common with standardized tests—NBME reuses a significant number of questions from prior exams on each exam form to “equate” USMLE scores (*i.e.*, adjust for variation in the difficulty of test forms so that scaled scores will reflect the same level of performance test-to-test). Ridgley Decl. ¶ 9; *see Nat’l Conf. of Bar Exam’rs v. Multistate Legal Studies*, 458 F. Supp. 2d 252, 254 (E.D. Pa. 2006) (“Because

² A “secure test” is “a nonmarketed test administered under supervision . . . all copies of which are accounted for and either destroyed or returned to restricted locked storage or secure electronic storage following each administration.” 37 C.F.R. § 202.13(b)(1).

plaintiff reuses many MBE questions, it goes to great lengths to maintain the secrecy of those questions.”); *Enow v. Nat’l Ass’n of Bds. of Pharmacy*, 2019 WL 6130747, at *4 (D. Colo. Nov. 19, 2019) (“[The National Association of Boards of Pharmacy] has a legitimate business interest in shielding past test questions from disclosure[.]”).

“[T]he unique nature of secure tests,” reflected in the special Copyright Office regulations, “means that *any* use [of the test questions] is destructive of [the test owner’s] rights” in those questions. *Educ. Testing Servs. v. Katzman*, 793 F.2d 533, 543-45 (3d Cir. 1986) (emphasis added) (affirming preliminary injunction prohibiting unauthorized use and disclosure of secure test questions, and finding that test owner would suffer irreparable harm absent an injunction). Courts have had little difficulty concluding that secure test questions constitute trade secrets. *See, e.g., United States v. Hedaihy*, 392 F.3d 580, 594 (3d Cir. 2004).

The unauthorized disclosure of secure questions from a licensing exam is harmful because it jeopardizes the validity of future exam results. Ridgley Decl. ¶ 11. “USMLE questions are intended to be disclosed only during actual test administrations and the unauthorized disclosure of those questions compromises the integrity of the examination.” *Nat’l Bd. of Med. Exam’rs v. Optima Univ.*, 2011 WL 7615071, at *1 (W.D. Tenn. Sept. 29, 2011); *cf. Detroit Edison Co. v. NLRB*, 440 U.S. 301, 304, 313 (1979) (explaining that “[t]est secrecy” is “critical to the validity” of tests used by employers).

Unauthorized disclosure harms not only test-takers and NBME, but also state licensing boards and the general public. Ridgley Decl. ¶ 11. Because “USMLE scores are relied upon by state medical boards when licensing doctors,” the “disclosure of secure, copyrighted test questions . . . presents the threat that persons without the skill and knowledge required to practice medicine will be licensed as a doctor.” *NBME v. Optima*, 2011 WL 7615071, at *11; *cf. Nat’l*

Conf. of Bar Exam'rs, 458 F. Supp. 2d at 262 (“By exposing . . . questions likely to appear on the MBE, [the defendant] undermined the integrity of the bar examination, possibly causing the admission of unqualified applicants.”).

This Court noted similar risks in enjoining the unauthorized disclosure of secure questions from the Medical College Admission Test (“MCAT”):

Obviously, continued use of copyrighted test questions by Multiprep could make worthless AAMC’s stock of MCAT questions. . . . Its procedures would not be capable of replenishing the valid test questions at a rate fast enough to allow continued administration of the MCAT in its present form. [T]he MCAT is a vital part of the medical school admissions process. . . . The receipt of even a large sum of money from the defendants would not adequately compensate AAMC and its member medical schools for the disruption in the medical school admission process. The evidence presented at the hearing by AAMC also suggested that there may be a finite number of acceptable basic science questions for the MCAT.

Ass’n of Am. Med. Colleges, 571 F. Supp. at 154-55.

Given the significant harm that can result from disclosing secure USMLE questions and answers, NBME goes to great lengths to keep them confidential. Ridgley Decl. ¶ 9. Beyond registering USMLE test materials with the United States Copyright Office under its secure test regulations, discussed above, examinees are subject to strict confidentiality obligations and must agree not to reproduce or disseminate any information relating to questions or answers from the exam. *Id.* ¶ 8. NBME has sanctioned examinees who did not respect the confidentiality of the exam, *id.*, and pursued litigation involving the unauthorized disclosure of USMLE test questions and answers, *see, e.g., NBME v. Optima*, 2011 WL 7615071, at *1.

U.S. Attorneys have also pursued criminal cases involving the unauthorized disclosure of such questions—underscoring that the potential injury transcends testing entities and threatens the public at large. *See, e.g., Ass’n of Am. Med. Colleges v. Mikaelian*, No. 83-2745, 1986 WL 332, *12-14 (E.D. Pa. March 18, 1986) (noting that defendant pled guilty to two criminal counts).

B. Cardinal Health and the West Virginia Opioid Litigation

The underlying two lawsuits were filed against Cardinal and other wholesale drug distributors in West Virginia courts over three years ago, then transferred to an MDL case pending in Ohio. *See* Cardinal Mot. at 1 (Dkt. No. 1) (citing *In Re Nat'l Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)). In January 2020, the cases were remanded to the Southern District of West Virginia for trial. *See id.* The two lawsuits (Dkt. Nos. 3:17-cv-1362 and 3:17-cv-1665) were consolidated in February and are referred to here, collectively, as the “West Virginia Lawsuit.”

Plaintiffs Cabell County Commission and the City of Huntington, West Virginia allege that “Cardinal Health failed to meet its suspicious order monitoring requirements [with respect to orders for opioids], failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law.” Third Am. Compl. ¶ 824, No. 3:17-cv-1362, ECF No. 80 (Sept. 10, 2019); *see also* N. Bowden et al., *The Opioid Epidemic in W. Va.*, Marshall University Digital Sch., at 1 (Apr. 2018) (“During the past seven years, major drug wholesalers including McKesson Corporation, Cardinal Health and AmerisourceBergen inundated the state with 780 million hydrocodone and oxycodone pills, which was equivalent to an astounding 433 opioid pills per resident in West Virginia.”). The plaintiffs’ allegations concern Cardinal’s conduct only between 2007 and 2012. Cardinal Mot. to Dismiss, No. 3:17-cv-1362, ECF No. 16, at 4 (March 2, 2017).

Cardinal denies the claims and has asserted 123 affirmative defenses. Cardinal’s Answer with Affirmative Defenses, at pgs. 434-52, No. 3:17-cv-1362, ECF No. 127 (Dec. 20, 2019).

C. Cardinal Subpoenas Non-Party NBME.

On March 27, 2020, Cardinal issued a subpoena in the Southern District of West Virginia demanding that NBME produce eight expansive categories of documents, dating back over 24

years, in just over two weeks. Cardinal Mem. in Support of Mot. to Compel (Dkt. 1-6) (“Cardinal Mem.”), Ex. A, at 1 (Dkt. No. 1-1). NBME served timely objections, pointing out, among other things, that its offices were closed due to the pandemic, and that NBME and its staff were extremely busy adjusting test delivery operations so that the USMLE—critical to licensing new physicians—can be taken during the ongoing public health crisis. *See id.*, Ex. C, at 1-2 (Dkt. No. 1-3); *see also* Ridgley Decl. ¶¶ 15-16. NBME’s offices in Philadelphia remain closed. *Id.* ¶ 13.

After a meet-and-confer between counsel, NBME agreed to produce two reports relating specifically to pain management questions on the USMLE, as well as 14 related documents. *See* Cardinal Mem. at 6. Following a second meet-and-confer call, NBME has agreed to produce additional documents relating to those two reports. *Id.* at 6 n.6.³

Cardinal now seeks to compel NBME to produce “[a]ll USMLE questions relating to pain management (and documents reflecting the correct answers),” *id.* at 6, from “January 1, 1996 through the present,” Cardinal Mem., Ex. A, Att. A, at 3. The subpoena includes definitions, but “questions relating to pain management” is undefined. *Id.*, Ex. A, Att. A, at 1-2.

Cardinal has also served a non-party deposition notice on NBME. *See Ex. A* to NBME’s Mot. to Quash. The subpoena calls for NBME to produce one or more 30(b)(6) witnesses who are “prepared to testify” about NBME’s communications, understandings, and activities over the past **24 years** relating to nine broad topics, with NBME defined to include anyone acting on its behalf, including “affiliates, programs, employees, directors, agents, contractors, representatives, board members, committees, subcommittees, working groups, and task forces.” *Id.*, Att. A. As revised, the subpoena sets the deposition for June 26, 2020. *See Ex. B* to NBME’s Motion to Quash.

³ Because NBME has agreed to produce, and will produce, the first category of documents identified in Cardinal’s Motion papers, this Court need not address Cardinal’s arguments concerning those documents. *See* Cardinal Mem. at 7-8 (Part II(C)).

ARGUMENT

This Court should deny Cardinal’s request to transfer its motion to compel production of non-party NBME’s secure USMLE test questions, deny that motion, and grant NBME’s cross-motion to quash Cardinal’s overbroad and unduly burdensome Rule 30(b)(6) subpoena.

I. The Court Should Deny Cardinal’s Motion to Compel.

A. No “exceptional circumstances” warranting transfer.

The threshold question is whether this Court should deny Cardinal’s request to transfer its motion to compel to the Southern District of West Virginia. Because Cardinal falls far short of showing “exceptional circumstances,” this Court should decline to transfer and decide the motion.

Rule 45 provides the rules for non-party subpoenas: if the non-party recipient of the subpoena objects, “the serving party may move the court for the district where compliance is required”—here, the Eastern District of Pennsylvania—“for an order compelling production.” Fed. R. Civ. P. 45(d)(2)(B)(i). Absent consent, the “court where compliance is required” may “transfer [the] motion . . . to the issuing court,” *i.e.*, the court where the action is pending, only “if the court finds *exceptional circumstances*.” Fed. R. Civ. P. 45(f) (emphasis added). “The proponent of the transfer bears the burden of showing exceptional circumstances.” *In re Novartis & Par Antitrust Litig.*, No. 2:19-MC-00149, 2019 WL 5722055, at *4 (E.D. Pa. Nov. 5, 2019).

Rule 45(f) is designed “[t]o protect local nonparties.” Fed. R. Civ. P. 45(f), Advisory Committee Notes (2013 amendments). “[*T*]he *prime concern*,” the Advisory Committee Notes explain, “*should be avoiding burdens on local nonparties* subject to subpoenas, and it should not be assumed that the issuing court is in a superior position to resolve subpoena-related motions.” *Id.* (emphasis added) (Rule 45 assures “local resolution of disputes about [non-party] subpoenas”).

Because NBME does not consent to transfer, transfer is warranted only if Cardinal establishes that exceptional circumstances exist. Cardinal comes nowhere near satisfying that heavy burden. Indeed, Cardinal dedicates *a single* sentence to arguing why the facts of this case present exceptional circumstances, vaguely referencing: (1) the “history and complexity of the opioid litigation,” (2) “the involvement of a Special Master who has background knowledge and established discovery procedures to evaluate discovery issues under a tight schedule,” and (3) “the centrality of the relevancy dispute to this motion.” Cardinal Mem. at 4. None of those three boilerplate arguments justify transferring the Motion.

First, this Court should reject Cardinal’s bald assertion that the complexity of the opioid litigation warrants a transfer. That complexity is only relevant to the extent it would assist in resolving the present motion to compel. But there is no indication it would. *Compare Garden City Emps.’ Ret. Sys. v. Psychiatric Sols., Inc.*, No. MISC.A. 13-238, 2014 WL 272088, at *3 & n.3 (E.D. Pa. 2014) (declining to transfer even though “the district court in Tennessee undeniably has greater familiarity with the Underlying Action and plaintiffs’ theory of liability” because the petitioner had failed “to identify any disputes similar to the one before this Court”), *with Parks, LLC v. Tyson Foods, Inc.*, No. MISC.A. 15-634, 2015 WL 5008255, at *2 (W.D. Pa. 2015) (“The [issuing court] is not only generally familiar with the facts and circumstances of this case due to the preliminary injunction proceedings that took place there, it is specifically familiar with the precise discovery dispute raised by defendant’s instant action to compel [compliance] with the subpoena.”). Saying that the underlying lawsuit is part of a complex MDL action does not dispense with the requirements of Rule 45. *See In Re: Nat’l Prescription Opiate Litig.*, 956 F.3d 838, 844 (6th Cir. 2020) (rejecting the notion that the Federal Rules are the “law in individual cases” but “merely hortatory in MDL ones”).

Second, simply observing that a Special Master is involved is likewise insufficient. *See* Cardinal Mem. at 4. Cardinal asserts that this Court must transfer its motion to compel to avoid interfering with the Special Master’s case management, but never says why. And although Cardinal asserts that the Special Master has “background knowledge,” it appears the Special Master was not appointed until March 2020, just over two months ago. *See* Order of Appointment, No. 3:17-cv-1362, ECF No. 200, at 1 (March 9, 2020).

Third, Cardinal maintains that understanding the relevancy of the USMLE questions is central to its motion (and weighs in favor of transfer) but, again, does not explain why. Cardinal Mem. at 4. The Court should reject Cardinal’s conclusory assertion for that reason alone but, in all events, relevancy is *not* central to the motion to compel. As set forth *infra*, Part I(B) (pgs. 15-20), this Court should deny the motion even assuming the information Cardinal sought is relevant.

Finally, even if there were a compelling reason to transfer, that reason must—but does not—“outweigh the interests of [NBME] in obtaining local resolution of the motion.” Fed. R. Civ. P. 45(f), Adv. Comm. Notes; *see In re Novartis*, 2019 WL 5722055, *5. It would be much more burdensome for NBME to litigate this issue in West Virginia instead of the Eastern District of Pennsylvania. Also, because NBME and other testing agencies are located in or near Philadelphia, this Court has dealt with secure exams and recognizes the risk of inappropriate disclosure.

If transferred to the issuing court, NBME would be swept up like a pebble in a raging river of unrelated discovery disputes that apparently must be decided by June 12, the current deadline for document discovery. *See* Def’s Mot. to Compel Third-Party Discovery, No. 3:17-cv-1362, ECF No. 436, at 4. Cardinal waited *years* to subpoena NBME. It would be burdensome and unfairly disadvantage NBME if Cardinal’s motion to compel were transferred to West Virginia at the close of discovery in that litigation, for that court to decide an issue involving an entity with

no connection to the case beyond being perceived as an impediment to proceeding to trial. *See In re Non-party Subpoenas to PPG Indus., Inc.*, No. 2:20-MC-00296-RJC, 2020 WL 1445844, at *3 (W.D. Pa. 2020) (noting that “Third Circuit courts have considered [whether] . . . the non-party has some connection to the proceeding” in “determining whether there are exceptional circumstances to transfer a matter under Rule 45(f)”).

Because no exceptional circumstances have been shown, Cardinal’s request to transfer should be denied. This Court is “well equipped to handle the motion.” *In re Novartis*, 2019 WL 5722055, *5.

B. The Court should deny Cardinal’s motion to compel production of confidential USMLE test questions and answers.

On the merits, this Court should deny Cardinal’s motion to compel—even assuming the secure test questions are relevant (and they are not)—because (1) Cardinal Health does not need them, (2) compliance would be unduly burdensome, and (3) the potential for harm caused by the production would outweigh any benefit.

A Rule 45 subpoena “must fall within the scope of proper discovery under [Rule 26(b)(1)],” *First Seaford Sur. v. Durkin & Devries Ins. Agency*, 918 F. Supp. 2d 362, 382 (E.D. Pa. 2013), which in turn limits the scope of discovery to “any nonprivileged matter that is relevant to a party’s claim of defense,” Fed. R. Civ. P. 26(b)(1). *See Frank v. Honeywell Int’l Inc.*, No. 15-MC-00172, 2015 WL 4770965, at *4 (E.D. Pa. 2015) (“A non-party may seek from the court protection from discovery via the overlapping and interrelated provisions of both Rules 26 and 45.”).

And while “the scope of discovery under the Federal Rules is unquestionably broad, this right is not unlimited and may be circumscribed.” *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999). It “does not authorize a party to simply engage in a fishing expedition.” *Garden City*, 2014 WL 272088, at *4. Rule 26 can be invoked “to shield the target of a discovery request

from ‘annoyance, embarrassment, oppression, or undue burden or expense,’” and even “broader restrictions may be necessary to prevent a non-party [like NBME] from suffering harassment or inconvenience.” *In re Novartis*, 2019 WL 5722055, *4.

As an initial matter, the documents sought are not relevant. Cardinal claims it “needs to see USMLE test questions and answers relating to pain management” because “USMLE questions *presumably* reflect the then-existing standards of care within the medical community.” Cardinal Mem. at 9-10 (emphasis added). But that argument is speculative and unfounded. “Subpoenaed information is not relevant to subject matter involved in the pending action if the inquiry is based on the party’s mere suspicion or speculation,” and “discovery may be denied where, in the court’s judgment, the inquiry lies in a speculative area.” *Saller v. QVC, Inc.*, No. CV 15-2279, 2016 WL 8716270, at *5 (E.D. Pa. 2016). That Cardinal wonders whether NBME’s highly confidential test questions might be helpful—three years into the case and as a last-minute shot in the dark launched at a non-party just before the discovery cutoff—is entirely speculative.

Cardinal’s surmising is also meritless (on various grounds). Cardinal’s theory that USMLE questions relating to “pain management” are relevant to its defense of the West Virginia Lawsuit necessarily assumes that those questions reflect the “changing standard of care” applicable to “the prescribing of opioid medications to treat chronic pain.” Cardinal Mem. at 5. But that premise is incorrect, and, regardless, that “standard of care” has nothing to do with Cardinal.

As initial matter, the premise that USMLE questions can be consulted to determine the “standard of care” for pain management is mistaken. Just as one would not look at contract questions that appeared on the Multistate Bar Examination to determine if a lawyer engaged in malpractice in drafting a contract, one would not look to USMLE questions relating to “pain management” to determine if a doctor inappropriately prescribed opioids in treating a patient.

The USMLE is designed to assess broad-based medical knowledge and evaluate minimum competencies; it is not intended to establish the standard of care for health care professionals. Ridgley Decl. ¶ 3. Unsurprisingly, no court has *ever* relied on the USMLE as reflecting the relevant standard of care for pain management or any other aspect of the delivery of healthcare. *Id.* Were it otherwise, NBME would be subject to a never-ending series of non-party subpoenas seeking production of its confidential exam questions in medical malpractice actions.

Further, the “standard of care” referenced in the motion to compel has nothing to do with Cardinal, or the underlying litigation, in any event, as Cardinal itself has explained:

Cardinal Health is a *wholesale distributor* of prescription drugs. It has no dealings with patients; it fulfills orders of pharmacies registered by the Drug Enforcement Administration (“DEA”) and duly licensed by the West Virginia Board of Pharmacy (“BoP”). Such pharmacies fill prescriptions written by doctors licensed to practice medicine by the West Virginia Board of Medicine. Cardinal Health does not manufacture opioids, nor does it have anything to do with advertising or marketing the drugs. It does not examine patients, diagnose the severity and causes of pain, or prescribe opioids—only a licensed doctor can do that—and it likewise has nothing to do with filling a doctor’s prescriptions—only licensed pharmacists do that[.]

Cardinal Mot. to Dismiss, at 1.

Cardinal now asserts that “NBME’s past exams will show what prospective doctors had to know about opioids and pain management before they could be licensed—and, in turn, why those doctors later prescribed opioids at the rate they did,” Cardinal Mem. at 1, but it apparently already knows why opioids were so liberally prescribed, and it had nothing to do with questions appearing on the USMLE. Cardinal represented in 2017 that opioids were liberally prescribed because “*federal health officials* over the past two decades recommended increased treatment of acute and chronic pain and year after year substantially increased the quota for hydrocodone and oxycodone that could be manufactured, distributed, and prescribed.” Cardinal Mot. to Dismiss, at 1.

And, according to Cardinal, the appropriateness of those prescriptions reflected decisions made by the DEA, the West Virginia Board of Pharmacy, and the West Virginia Board of Medicine, all of which Cardinal referenced in its motion to dismiss the West Virginia Lawsuit (with no mention of the USMLE), and all of which have received third-party document subpoenas from Cardinal or its co-defendants in the West Virginia Lawsuit.

More than 30 other non-parties have received subpoenas from Cardinal or its co-defendants. Def's Mot. to Compel Third-Party Discovery, at 1-4. Consistent with Cardinal's own theory of the case, documents from those other third-parties might explain why doctors in West Virginia "prescribed opioids at the rate they did" in the years at issue in the lawsuit. *See* Cardinal Mem. at 1. Highly confidential questions and answers from the USMLE will not.

Because Cardinal has no legitimate need to obtain secure USMLE questions from NBME and disclosing such questions would cause significant harm, there is nothing untoward about NBME wanting to keep its "exams secret, even in the midst of immensely consequential litigation regarding a major societal problem." *Id.* at 2. Cardinal does not need access to confidential USMLE questions dealing with "pain management" to explain why West Virginia doctors prescribed opioids at the rates they did. And there is certainly no reason it would need 24+ years of questions when the claims against Cardinal relate only to a five-year period (2007-2012).

"Even if the information sought [were] relevant, discovery is not allowed where no need is shown, or where compliance is unduly burdensome, or where the potential harm caused by production outweighs the benefit." *Avago Techs. U.S., Inc v. IPtronics Inc*, 309 F.R.D. 294, 296 (E.D. Pa. 2015). All three circumstances apply here.

First, Cardinal has not demonstrated a need for the confidential test questions. *See Frank*, 2015 WL 4770965, at *5 (quashing subpoena because, although the evidence sought was relevant,

it was not needed); *Avago*, 309 F.R.D. at 299 (same). It does not explain why the so-called “changing standard of care” cannot be shown in other, more compelling ways, using alternative sources—and there are many. *See In re Novartis*, 2019 WL 5722055, at *7 (“Courts should also consider what information is available to the requesting party from other sources,” and, “[t]o that end, the requesting party should be able to explain why it cannot obtain the same information, or comparable information that would also satisfy its needs, from one of the parties to the litigation—or, in appropriate cases, *from other third parties that would be more logical targets for the subpoena.*”) (emphasis added).

Here, there are much more logical targets for the information Cardinal seeks. For example, exams relating specifically to pain management and pain medications would be far more informative (although the entities that develop those exams would likely not want to disclose their secure questions either),⁴ as would *publicly available* information from entities like the FDA,⁵ the CDC,⁶ boards that provide practice guidelines that specifically address pain management,⁷ state regulations and advisory guidelines,⁸ or accreditation bodies for medical residency programs,

⁴ *See, e.g.*, the American Board of Pain Medicine (www.abpm.org/ce), the American Board of Interventional Pain Physicians (www.abipp.org/exams), and the American Society of Addiction Medicine (www.asam.org/education/certification-MOC).

⁵ *See, e.g.*, U.S. Food & Drug Admin., *Timeline of Selected FDA Activities & Significant Events Addressing Opioid Misuse and Abuse*, www.fda.gov/media/126835/download.

⁶ *See, e.g.*, U.S. Dep’t of HHS, *CDC Guideline for Prescribing Opioids for Chronic Pain*, Vol. 65 (March 2016), www.cdc.gov/media/modules/dpk/2016/dpk-pod/rr6501e1er-ebook.pdf.

⁷ *See, e.g.*, D., Ernstzen et al., *Clinical Practice guidelines for the Mgmt. of Chronic Musculoskeletal Pain in Primary Healthcare: a Systematic Review*, 12 J. Implementation Sci. 1 (2017), www.ncbi.nlm.nih.gov/pmc/articles/PMC5217556/; P. Recupero, *Clinical Practice Guidelines as Learned Treatises: Understanding Their Use as Evidence in the Courtroom*, 36 J. of the Am. Academy of Psychiatry and the Law Online 290 (2008).

⁸ *See, e.g.*, C. Davis, The Network for Pub. Health Law, *State-by-State Summary of Opioid Prescribing Regulations & Guidelines* at 6, 59-61 (outlining relevant statutes, regulations, and guidelines on prescribing opioids in West Virginia and other jurisdictions).

which drive instruction on core competencies for students completing their final years of graduate medical education.⁹ There is a laundry list of logical places one might look to understand the relevant standard of care, and NBME's bank of test questions is not one of them.

Second, complying with Cardinal's subpoena would be unduly burdensome. *See* Fed. R. Civ. P. 45(d)(3)(A), (iv) (“[T]he court . . . *must* quash or modify a subpoena that . . . subjects a person to undue burden.” (emphasis added)); *Avago*, 309 F.R.D. at 297 (“undue burden” arises where the subpoena “would require a non-party to incur excessive expenditure of time or money”). Cardinal's subpoena, even as currently narrowed, would impose an undue burden on NBME.

Identifying and producing responsive USMLE test questions would be burdensome under any circumstances but is especially difficult now, when NBME's offices are closed under a stay-at-home order and NBME is devoting significant man-hours toward exploring and implementing ways to administer its multiple-choice and clinical-skills exams in a safe but timely manner. Ridgley Decl. ¶¶ 13, 15-16. Many staff are busy creating new test forms so students can test at medical schools, while also accounting for special groups of test-takers, such as international medical students and disabled examinees who request accommodations. *Id.* ¶ 16.

If compelled to produce test questions, NBME would first need to identify those responsive to Cardinal's subpoena, *i.e.*, questions “relating to pain management.” *Id.* ¶ 17. “Pain management” is a vague term in the context of a broad medical licensing exam, where questions routinely involve conditions that might cause pain. *Id.* “Pain” might be addressed, and thus indirectly “managed,” by any number of treatments unrelated to opioids, another pain medication, or a specific intention to manage pain. Many USMLE questions refer to pain but have nothing to do with “pain

⁹ *See, e.g.*, Accreditation Council for Graduate Med. Educ., Common Program Requirements (2019) (Requirement IV.C.2 addresses “instruction in pain management” and addiction), <http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRResidency2019.pdf>.

management,” and even a smaller fraction involve addressing pain. *Id.*, *see, e.g.*, Cardinal Mem., Ex. D, at 449, 452, 455 (article on 2014 review of USMLE content for which documents have already been produced to Cardinal, concluding that 27.7% of questions from a sampling of USMLE exams used the word “pain,” but only 15.4% actually tested for pain content, and “[o]nly a small minority of [those] questions addressed what to do once pain was recognized”).

NBME would have to search its question bank of tens of thousands of “live,” reusable questions for those including the term “pain” (which, based on the experience with the review discussed above, could be around 25 percent).¹⁰ Ridgley Decl. ¶ 18. And because only a relatively small percentage of questions that mention “pain” are responsive—that is, concern “what to do once pain was recognized,” Cardinal Mem., Ex. D, at 449, 452, 455—NBME would need to evaluate each of the thousands of questions that mention “pain.” Ridgley Decl. ¶ 18.

The process described above would be time-consuming and expensive. It would likely require at least three NBME staff members (one for each Step exam) and at least one technical expert, likely working nights and weekends, and could take them up to 12 weeks even with questions in an electronic format. *Id.* ¶ 21. That would likely exceed \$75,000 in lost staff time. *Id.* ¶ 22. Cardinal’s assertion that “it should not be difficult to search for and produce those related to pain management” is thus categorically wrong. *See* Cardinal Mem. at 10.

Third, the potential harm to non-party NBME would outweigh any theoretical benefit to Cardinal. Courts “should be particularly sensitive to weighing the probative value of the

¹⁰ Searching is significantly more difficult amidst the pandemic because NBME employees are working remotely and cannot access questions in the usual manner. Ridgley Decl. ¶ 19. Moreover, if they exist at all, exams from 1996 through 1999 exist primarily in paper copy and therefore cannot be electronically searched for specific terms. *Id.* ¶ 20. Identifying responsive questions from those years would require tracking down those paper-based exams, assuming that is possible, and reading the *entire* exams, question-by-question, to identify items that reference “pain.” *Id.* Judgments would then need to be made on which of those questions relate to “pain management.”

information sought against the burden of production on a non-party.” *Frank*, 2015 WL 4770965, at *4 (where non-party is the subject of discovery, “courts may impose broader restrictions[.]”).

Cardinal’s motion to compel not only seeks discovery from a non-party, but it requests secure test questions, which, to the best of NBME’s knowledge, have *never* been produced as part of a lawsuit. *See* Ridgley Decl. ¶ 12; Fed. R. Civ. P. 45(d)(3)(B)(i) (courts may quash or modify a subpoena “if it requires disclosing a trade secret or other confidential research, development, or commercial information”). As discussed above, any unauthorized disclosure of USMLE questions would harm not only NBME, which invests significant time and money developing these questions, but also examinees, licensing boards, and the general public. *See supra*, Part A (pgs. 3-6); *cf. Nat’l Conf. of Bar Exam’rs*, 458 F. Supp. 2d at 262 (“States have a compelling interest in regulating admission to the bar both to maintain the integrity of the legal system and to protect the safety of their citizens,” and “the victims of [an unauthorized disclosure] are impossible to identify and the injury impossible to quantify”); *Enow v. NABP*, 2019 WL 6130747, at *6 (denying motion to compel production of secure questions because of burden and risk of harm to the testing entity).

NBME has a finite number of questions and answer sets relating to addressing pain through opioids, other drugs, or other means. Exposing these items would compromise NBME’s ability to use those questions on future exams, and reduce the extent to which the use of opioids and other forms of “pain management” can be tested on the USMLE. *See Ass’n of Am. Med. Colleges*, 571 F. Supp. at 155-56.

Because the protective order in the underlying lawsuit is inadequate to mitigate these substantial and far-reaching harms, *see infra* Part I(C), this risk alone “presents significant hardships—especially in light of [NBME’s] non-party status in this action.” *PPL Energy Plus, LLC v. Solomon*, No. CV 11-745-PGS 2013, WL 12123337, at *5 (D.N.J. 2013) (concluding that

“any potential benefit to Plaintiffs would be outweighed by the hardships to [non-party subpoena recipient] and the public”). The Protective Order would permit disclosure of secure test questions and answers to literally *thousands* of individuals, a number that in itself arguably warrants retiring the questions from use on future USMLE exams and, in all events, creates an enormous risk of inadvertent disclosure that would unquestionably require retiring such questions.

C. The Protective Order in the underlying litigation does not warrant compelling NBME to produce secure USMLE test questions.

Cardinal argues that NBME should not be concerned about turning over its most valuable assets in response to the subpoena because “NBME can designate materials as ‘confidential’ pursuant to the Protective Order” that governs the underlying lawsuit, which purportedly “provides multiple layers of protection,” none of which are described. Cardinal Mem. at 10. In reality, the Protective Order provides little or no meaningful protection.

The Protective Order distinguishes between materials designated “Confidential” and “Highly Confidential.” Cardinal Mem., Ex. E (Dkt. No. 1-5) (“Protective Order”), at ¶¶ 10, 11. Assuming secure questions from a licensing exam warrant a “Highly Confidential” designation, the Protective Order would permit disclosure of the secure test questions to:

- Outside and in-house counsel of any Plaintiff or Defendant involved in the Litigation—which is *not limited to the West Virginia case in which the NBME documents have been subpoenaed as is defined instead as the MDL case* from which the West Virginia case was remanded for trial, *In re: National Prescription Opiate Litigation* (MDL No. 2804)—and any of their staff working on the Litigation;
- Vendors to any party or counsel for any party in the Litigation, and their staff;
- Court reporters who transcribe testimony in the Litigation, and their staff;
- The Court(s) and any Special Masters in the Litigation, and their staff;
- Formally retained independent experts and/or consultants in the Litigation;
- State or federal law enforcement agencies;

- Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 (which, as noted, is not the West Virginia case in which the NBME documents have been subpoenaed); and
- Witnesses during depositions.

Id. ¶ 34.

These categories alone would permit disclosure of NBME's confidential licensing exam questions to hundreds—if not thousands—of individuals, depending on the number of parties, law firms, vendors, experts, consultants, court reporters, and courts involved in MDL 2804. But the permitted disclosures would not end there. Once Cardinal obtained copies of secure USMLE questions, those questions might be responsive to discovery requests that Cardinal receives (or has received) in one or more of the “*thousands of cases* around the country” that Cardinal is currently defending in connection with its distribution of opioid products. *See* Cardinal Mem. at 1 (emphasis added). If that happened, the questions could apparently be disclosed by Cardinal to potentially thousands of *additional* individuals without violating the Protective Order, which permits disclosure of Highly Confidential documents to counsel for *any* claimants in *any* litigation pending outside the “Litigation” that arises from Cardinal's “distribution of opioid products.” *Id.* ¶ 34(j).

Finally, the Protective Order apparently does not apply to the use of Highly Confidential documents at trial, *id.* at ¶ 65, and “may be amended without leave of the Court by ... Outside Counsel for the Parties,” *id.* at ¶ 83—two more reasons why this Court should attach little significance to the Protective Order.

In short, the Protective Order provides insufficient protection to warrant compelling NBME to produce secure USMLE exam questions. *Cf. Detroit Edison v. NLRB*, 440 U.S. at 316-17 (stressing the “scant protection to the Company's undisputed interests in test secrecy” and “danger of inadvertent leaks,” and holding that the NLRB “abused its discretion in ordering the Company to turn over [its confidential] test battery and answer sheets”).

D. If production is nonetheless required, the Court should limit NBME's production obligation.

If the Court concludes that Cardinal is entitled to receive any test questions from NBME, NBME respectfully requests that (i) the required production be limited to the questions described below; (ii) NBME be given at least six (6) weeks from the date of the Court's order to retrieve and produce these questions to Cardinal; and (iii) NBME's production obligation be limited in the first instance to producing the questions for inspection by Cardinal's outside counsel at NBME's offices in Philadelphia, with any subsequent production of such questions only pursuant to a protective order that relates specifically to the disclosure and use of those questions in connection only with the West Virginia Lawsuit (such protective order to be negotiated and agreed upon in good faith by NBME's counsel and Cardinal's counsel if Cardinal's counsel ultimately decides to use the questions in defending the West Virginia Lawsuit, and with all copies of the questions returned or destroyed upon completion of the litigation).

Cardinal states that during the meet-and-confer process, it "attempted to reduce any burden on NBME arising from this [document] request" by inquiring "as to NBME's position on producing three sub-categories of USMLE questions: (1) questions that have been retired from use on the USMLE due to age, obsolescence, or some other reason; (2) questions that were tested on the USMLE but not scored for psychometric or other reasons; and (3) questions that were previously disseminated to the public as samples." Cardinal Mem. at 10. If the Court orders NBME to produce any questions to Cardinal, they should be limited to USMLE "pain management" questions and answers that fall within one of these three sub-categories. While some of these questions might be used on other assessments that NBME develops, and thus still warrant designation as confidential, they will not be used on future USMLE exam forms. Ridgley Decl. ¶ 10. Limiting disclosure of test questions to these three sub-categories will respect the security

of questions that will be used on future USMLE exams, thereby protecting the integrity of a test that jurisdictions rely upon in making licensure decisions.

Finally, if the Court orders NBME to produce any questions, NBME should be required to produce only questions administered in the five-year window that mirrors the plaintiffs' claims against Cardinal in the West Virginia Lawsuit (2017-2012).

II. The Court Should Quash Cardinal's Rule 30(b)(6) Deposition Subpoena.

Cardinal's 30(b)(6) deposition subpoena calls for NBME to prepare and produce one or more witnesses—while its offices might be closed, and to the considerable detriment of efforts to administer USMLE licensing exams in the midst of the pandemic—to testify regarding nine broad categories of information, each covering the last 24 years:

1. Your efforts related to the creation, revision, testing, and grading of content related to pain management (including the monitoring, measuring, and treatment of pain by healthcare professionals) and/or Prescription Opioids on the [USMLE] or other medical licensing examinations, from 1996 to the present.
2. Your efforts, including those of any committee, subcommittee, working group, review group, or task force, to develop or review content or questions for the USMLE or other medical licensing examinations related to pain management (including the monitoring, measuring, and treatment of pain by healthcare professionals) and/or Prescription Opioids, from 1996 to the present.
3. Your communications about and understanding of the changing standard of care in the medical field relating to pain management and/or the prescribing of Prescription Opioids, from at least 1996 to the present.
4. Your communications about pain management (including the monitoring, measuring, and treatment of pain by healthcare professionals) and/or the prescribing of Prescription Opioids, including but not limited to communications with any federal, state, or local legislative, administrative, regulatory, or enforcement bodies concerning pain management, from 1996 to the present.
5. Any actions You took, or considered taking, with respect to pain management (including the monitoring, measuring, and treatment of pain by healthcare professionals) and/or the prescribing of Prescription Opioids, from 1996 to the present.
6. Any discussions You participated in, observed, or became aware of during any public or non-public meeting of NBME, including any committees or subcommittees thereof, about

Prescription Opioids or practices regarding pain management (including the monitoring, measuring, and treatment of pain by healthcare professionals), from 1996 to the present.

7. Your efforts to create, approve, or disseminate publications and/or examination materials concerning the use, risks, or benefits of medications used for pain management (including the monitoring, measuring, and treatment of pain by healthcare professionals), including Prescription Opioids, from 1996 to the present.
8. Your efforts to analyze the use of Prescription Opioids to treat chronic pain, including by creating prescribing guidelines or making any revisions thereto, from 1996 to the present.
9. Your understanding of the legitimate need for and/or use of Prescription Opioids, including the benefits and/or medical uses of prescription opioid medications, from 1996 to the present.

See **Ex. A** to NBME's motion to quash, Att. A. The subpoena is facially unreasonable and should be quashed.

The Court must quash or modify a subpoena that "subjects a person to undue burden." Fed. R. Civ. P. 45(d)(3)(A)(iv). This Court also "recognize[s] that '[d]iscovery should be more limited to protect non-party deponents from harassment, inconvenience or disclosure of confidential documents.'" *Frank Brunckhorst Co. v. Ihm*, No. 12-mc-0217, 2012 WL 5250399, at *5 (E.D. Pa. 2012); *In re Auto. Refinishing Paint*, 229 F.R.D. 482, 495 (E.D. Pa. 2005).

Given NBME's non-party status, the breadth of the topics Cardinal wants one or more NBME employees to address on the company's behalf (covering a period of over two decades), the limited need for testimony from an NBME witness on those topics, the limited relevance (if any) of that testimony, and disruption such a deposition (or depositions) would cause relative to the competing work obligations of NBME staff in the current pandemic, the deposition notice should be quashed as unduly burdensome to NBME.

Courts routinely quash 30(b)(6) subpoenas under similar circumstances. *See, e.g., Stiles v. Walmart Inc.*, 2020 WL 1976426, at *8 (S.D. Ohio 2020) (quashing subpoena that was "not appropriately proportional to the claims at issue," and "based upon P&G's non-party status and

the tangential and extremely limited relevance of the discovery sought”); *Maxtena, Inc. v. Marks*, 289 F.R.D. 427, 439 (D. Md. 2012) (quashing 30(b)(6) deposition subpoena where the information sought was not necessary and was confidential in nature, “such that its disclosure . . . could have harmful results,” and the non-party “would incur substantial expense to prepare and send a corporate representative”); *Reeves v. Town of Cottageville*, 2014 WL 197743, at *2 (D.S.C. 2014) (quashing subpoena where certain topics were overly broad and unduly burdensome, and the rest were duplicative of information already provided by the non-party); *Gen. Foods Corp. v. Computer Election Sys., Inc.*, 1980 WL 30300, at *1 (S.D.N.Y. 1980) (quashing 30(b)(6) subpoena covering 20-year period, as it was “entirely too broad and burdensome”);.

Alternatively, the Court should modify the 30(b)(6) subpoena such that (1) it is limited to the five years for which Cardinal’s actions are at issue in the West Virginia Lawsuit (2007-2012), (2) the definition of “NBME” in the subpoena does not include individuals or entities with whom NBME is or has been affiliated and is instead limited to NBME itself, and (3) the topics to be addressed are limited to the assessment of the use of opioids, other prescription drugs, or other means of managing pain on the USMLE Step 1, Step 2 CK, or Step 3 exams.

CONCLUSION

The Court should deny Cardinal’s request that its motion to compel be transferred to the U.S. District Court for the Southern District of West Virginia, deny Cardinal’s motion to compel, and grant NBME’s motion to quash Cardinal’s Rule 30(b)(6) deposition subpoena.

Dated: May 29, 2020

By: /s/ Michael E. Sacks

Michael E. Sacks (Pa. Bar No. 39774)
Hamburg & Golden, P.C.
1601 Market Street, Suite 3310
Philadelphia, PA 19103-1443
Phone: 215-255-8596
Facsimile: 215-255-8583
sacksme@hamburg-golden.com

Robert A. Burgoyne (*pro hac vice*
application forthcoming)

Perkins Coie LLP

700 Thirteenth Street, N.W., Suite 800

Washington, D.C. 20005-3960

Phone: 202-654-6200

Facsimile: 202-654-6211

RBurgoyne@perkinscoie.com

*Attorneys for National Board of Medical
Examiners*

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed on May 29, 2020, via the Court's CM/ECF System, which will send notification of such filing to counsel of record for Plaintiff.

/s/ Michael E. Sacks
Michael E. Sacks

Attorney for Defendant NBME